FDA 510(k) Premarket Notification

K873786 SMITH & NEPHEW DAYLIGHTER(TM)

CLEARED

Oct 23, 1987
36 days to decision

K873786 · Product code: **FSY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k873786/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Surgical, Ceiling Mounted (FSY)
Date received	Sep 17, 1987
Decision date	Oct 23, 1987
Days to decision	36 days
Third-party review	No

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	KEVIN RANDICH
Website	http://www.smith-nephew.com/
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k873786/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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